APR 17 2012

510(k) Summary **3mensio Workstation** **[QA693]v2.0**

Submitter Name	Pie Medical Imaging BV
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Preparation Date	31 January 2012
Trade Name	3mensio Structural Heart / 3mensio Vascular
Common Name	3mensio Workstation
Regulation Class	Class II (21 CFR, part 892.2050, LLZ)
Classification Name	Picture Archiving and Communications System
Predicate Devices	3vision/surgery, cleared under K072653
Device Description	3mensio Workstation is a stand-alone software application intended to run on a PC with a Windows operating system. It allows Cardiologists, Radiologists and Clinical Specialists to select patient studies from various data sources, view them, and process the images with the help of a comprehensive set of tools. The 3mensio Workstation contains two modules, 3mensio Structural Heart and 3mensio Vascular, which can be marketed in combination or as separate solutions. 3mensio Structural Heart enables assessment and measurement of different structures of the Heart, e.g. aortic valve, mitral valve, ventricles. It provides simple techniques to assess the feasibility of a transapical, transfemoral or subclavian approach to structures for replacement or repair procedures. 3mensio Vascular enables assessment of vessels and can help the physician identify calcifications, aneurysms and other anomalies to quickly and reliably prepare for various types of vascular surgery. The 3mensio Workstation can combine 2D scan slices into comprehensive 3D models of the patient, and can display supporting ultrasound and X-ray Angio data. The software accurately represents different types of tissue, making it easier to diagnose anomalies in scans. 3mensio Workstation works with all major medical image formats and can access multiple data stores and across networks.
Intended Use	3mensio Workstation is a software solution that is intended to provide Cardiologists, Radiologists and Clinical Specialists additional information to aid them in reading and interpreting DICOM compliant medical images of structures of the heart and vessels. 3mensio Structural Heart enables the user to: • Visualize and measure (diameters, lengths, areas, volumes, angles) structures of the heart and vessels • Quantify calcium (volume, density) 3mensio Vascular enables the user to: • Visualize and assess stenosis, aneurisms and vascular structures • Measure the dimensions of vessels (diameters, lengths, areas, volumes, angles)

Indications for use:

3mensio Workstation enables visualization and measurement of structures of the heart and vessels for:

- Pre-operational planning and sizing for cardiovascular interventions and surgery
- Postoperative evaluation

To facilitate the above, the 3mensio Workstation provides general functionality such as:

- Segmentation of cardiovascular structures
- Automatic and manual centerline detection
- Visualization and image reconstruction techniques: 2D review, Volume Rendering, MPR, Curved MPR, Stretched CMRP, Slabbing, MIP, AIP, MinIP
- Measurement and annotation tools
- Reporting tools

Technological Characteristics Comparison

The technological comparision table shows the equivalence between the 3mensio Workstation software and the predicated device.

New Device	Predicate Device
3mensio Workstation Pie Medical Imaging K120367	3viseon/surgery 3mensio K072653
Interface to image sources • DICOM image data	Interface to image sources • DICOM image data
Import of Patient Data • Manual through keyboard/mouse • Automatic import with image file • Study List creation	Import of Patient Data • Manual through keyboard/mouse • Automatic import with image file • Study List creation
Study list image functionality • Exporting • Deleting • Anonymizing (no automatic deletion of original patient data) • Search	Study list image functionality • Exporting • Deleting • Anonymizing (no automatic deletion of original patient data) • Search
Image processing: • Realign orthogonal MPRs • Segmentation toolset: - Automatic segmentation - Automatic centreline - Manual centreline - Centreline editing • Undo/redo operations • Volume sculpting	Image processing: • Realign orthogonal MPRs • Segmentation toolset: - Automatic segmentation - Automatic centreline - Manual centreline - Centreline editing • Undo/redo operations • Volume sculpting
Image assessment: • Linear (length and diameter), angular and ROI measurements • Volume measurements • C-Arm angulation calculation • Text and arrow annotations • Calcium scoring for assessment of calcium in the aortic root	Image assessment: • Linear (length and diameter), angular and ROI measurements • Volume measurements • C-Arm angulation calculation • Text and arrow annotations • Calcium scoring in vasculature
Image display: • Orthogonal, oblique, double oblique, curved, cross-curved, stretched MPR rendering • MIP, AveIP, MinIP and color volume slabs • MIP volume rendering	Image display: • Orthogonal, oblique, double oblique, curved, cross-curved, stretched MPR rendering • MIP, AveIP, MinIP and color volume slabs • MIP volume rendering

New Device	Predicate Device
3mensio Workstation Pie Medical Imaging K120367	3viseon/surgery 3mensio K072653
• Color volume rendering • Grayscale volume rendering • 2D slice review and stack comparison • 4D cine • Interactive VOI clipping • Multi-tissue color and opacity control • Active presets User-defined presets	• Color volume rendering • Grayscale volume rendering • 2D slice review and stack comparison • 3D view • Interactive VOI clipping • Multi-tissue color and opacity control • Active presets • User-defined presets
• DICOM Support: • Compatible with all scanner vendor DICOM datasets • Storage SCP • Import DICOM files • DICOM compliance for CT, enhanced CT, MRI, enhanced MRI, XA, Nuclear Medicine, CR, SC, and Ultrasound images • Import from DICOMDIR • Storage SCU • Query/retrieve SCU • Automatic grouping of images into volumes • Windows printing or send to PACS	DICOM Support: • Compatible with all scanner vendor DICOM datasets • Storage SCP • Import DICOM files • DICOM compliance for CT, MRI, XA, Nuclear Medicine, CR, SC, and Ultrasound images • Import from DICOMDIR • Storage SCU • Query/retrieve SCU • Automatic grouping of images into volumes • Windows printing or send to PACS
• Storage of Results • Printout • Session state • PDF format • DICOM PDF report	Storage of Results • Printout • Session state • PDF format • DICOM SC report
• MS Windows	• MS Windows

Performance Data

3mensio Workstation is developed and tested by 3mensio Medical Imaging according to their Quality Assurance system.Testing includes software verification and validation. The tests were made to evaluate the 3mensio Workstation and yield accuracy and precision results within the predetermined specifications.
3mensio Workstation is produced and marketed under the responsibility of manufacturer Pie Medical Imaging.

Substantial Equivalence

The intended use and technological characteristics of 3mensio Workstation are substantial equivalent to the intended use and technological characteristics of the predicate device.

Conclusion

The testing reported in this 510(k) establishes that 3mensio Workstation is substantial equivalent to the predicate device and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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APR 17 2012

Re: K120367
Trade/Device Name: 3mensio Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications System
Regulatory Class: II
Product Code: LLZ
Dated: January 31, 2012
Received: February 6, 2012

Dear Ms. Daniels:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K120367

Indications for Use

510(k) Number:

Device Name: 3mensio Workstation

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Prescription Use ____√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K120367